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David V. Upite	47-147
Name of Attorney/Agent	Registration No.
Signature of Attorney or Agent	

P&G Case 8543D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :
 Ji-In Kim Alstead et al. : Confirmation No.
 Serial No. : Group Art Unit
 Filed September , 2003 : Examiner

For Medicinal Uses of Hydrazones

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
 P. O. Box 1450
 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made below in a Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☒ 37 C.F.R. §1.97 (b)(1) - U.S. Direct (within 3-months of filing a regular application or converted provisional)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(1), is being filed within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☐ 37 C.F.R. §1.97 (b)(2) - Via PCT (within 3 mo. of Nat'l Stage Entry)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(2), is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application. Therefore, no fee is believed to be due.

3. ☐ 37 C.F.R. §1.97 (b)(3) - (>3 mo. after filing direct or nat'l stage entry, but before 1st O.A.)

This information disclosure statement is being submitted under 37 C.F.R. §1.97 (b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter is enclosed to facilitate charging of the fee, if necessary.

THE FOLLOWING IS ADDITIONAL INFORMATION PERTAINING TO (2) OR (3) MARKED WITH AN (X) ABOVE.

(a) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that both a copy of the International Search Report and copies of the references cited therein are present in the national stage file. In accordance with MPEP §1893.03(g), it is respectfully requested that the Examiner note the consideration of these references in the first Office Action via the PTO-892 form.

(b) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that a copy of the International Search Report is present in the national stage file. Copies of the references cited in that report are enclosed.

(c) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 does not indicate that a copy of the International Search Report and copies of the references cited are present in the national stage file. Copies of the International Search Report and references are attached.

4. ☐ 37 C.F.R. §1.97 (b)(4) - (before the mailing of a first Office Action after the filing of a request for continued examination under §1.114)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(4), is being filed with the Request for Continued Examination (RCE) under 37 C.F.R. §1.114.

5. ☐ Information to be Considered with CPA Filing. This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 CFR 1.53(d).

6. ☐ 37 C.F.R. §1.97(c) with fee payment - (use after 1st Office Action & before Final Office Action or Notice of Allowance)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:

☒ (1) Copies of the cited references were previously cited by or submitted to the USPTO in prior application Case No. 8543, U.S. Patent Application Serial No. 10/134,890, filed 04/29/2002. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of those documents are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d).

OR

☐ (2) Copies of the cited documents are enclosed.

OR

☐ (3) Copies of all said documents, except document No.'s _____, were submitted and considered in parent application U.S. Patent Application Serial No. _____, filed _____. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of document No.'s _____ are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of document No.'s _____ are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

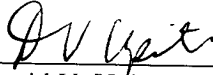
☐ (4) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

☐ (5) Applicants also respectfully request the Examiner to consider and make of record the copending applications listed on the attached page.



Additional information is attached.

Respectfully submitted,

By 
David V. Upite
Attorney or Agent for Applicant(s)
Registration No. 47, 147
(513) 622-1825

Date: September 12, 2003

Customer No. 27752

(IDS.doc)
(Last Revised 4/4/2003)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	COMPLETE IF KNOWN	
	Application Number	10/134,890
	Confirmation Number	5263
	Filing Date	04/29/2002
	First Named Inventor	Ji-In Kim Almstead
	Group Art Unit	1614
	Examiner Name	
SHEET 1 of 3	Attorney Docket Number	8543

U. S. PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. ¹	DOCUMENT NUMBER		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ²	(if known)			
	1	US-5,822,914		03/16/1999	Semenza	
	2	US-6,020,462		02/01/2000	Semenza	
	3	US-5,073,492		12/17/1991	Chen et al.	
	4	US-5,194,596		03/16/1993	Tischer et al.	
	5	US-5,219,739		06/15/1993	Tischer et al.	
	6	US-5,985,913		11/16/1999	Williams et al.	
	7	US-4,997,835		03/05/1991	Schaper et al.	
	8	US-5,942,527		08/24/1999	Kadaba et al.	
	9	US-6,329,378 B1		12/11/2001	Mei et al.	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. ¹	FOREIGN PATENT DOCUMENT			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	10	WO	00/10578 A1		03/02/2000	The Johns Hopkins U. School of Medicine		
	11	WO	98/17267 A1		04/30/1998	Zymogenetics, Inc.		
	12	WO	97/15308 A1		05/01/1997	Zymogenetics, Inc.		
	13	WO	88/00047 A1		01/14/1988	Scripps Clinic and Research Foundation		
	14	EP	0315434 A2		05/10/1989	Yissum Research and Development Co. of the Hebrew U. of Jerusalem		
	15	WO	02/16315 A1		02/28/2002	Merck Patent GMBH		

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	16	BUN et al., "Oxygen Sensing and Molecular Adaptation of Hypoxia", <u>Amer. Physiological Society</u> , 1996, pp. 839-885, Vol. 76, No. 3.	
	17	SEMENZA, "Regulation of Mammalian O ₂ Homeostasis by Hypoxia-Inducible Factor 1.", <u>Annu. Rev. Cell Dev. Biol.</u> , 1999, pp. 551-578, Vol. 15.	

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¹Applicant's unique citation designation number (optional). ²See Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p> <p>SHEET 2 of 3</p>	COMPLETE IF KNOWN	
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	Filing Date	04/29/2002
	First Named Inventor	Ji-In Kim Almstead
	Group Art Unit	1614
	Examiner Name	
	Attorney Docket Number	8543

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	18	SHWEIKI et al., "Induction of vascular endothelial growth factor expression by hypoxia and by glucose deficiency in multicell spheroids: Implications for tumor angiogenesis", <i>Proc. Natl. Acad. Sci.</i> , 1995, pp. 768-772, Vol. 92.	
	19	SEMENZA, "HIF-1: mediator of physiological and pathophysiological responses to hypoxia", <i>J. Appl. Physiol.</i> , 2000, pp. 1474-1480, Vol. 88.	
	20	SEMENZA, "Hypoxia-inducible factor 1: master regularor of O ₂ homeostasis", <i>Genetics & Development</i> , 1998, pp. 588-594, Vol. 8.	
	21	JIANG et al., "Transactivation and inhibitory domanins of hypoxia-inducible facer 1 α ", <i>J. Biol. Chem.</i> , 1997, pp. 19253-19260, Vol. 272, No. 31.	
	22	JIANG et al., "Dimerization, DNA binding, and transactivation properties of hypoxia-inducible factor 1", <i>J. of Biol. Chem.</i> , 1996, pp. 17771-17778, Vol. 271, No. 30.	
	23	PEARLMAN et al., "Magnetic resonance mapping demonstrates benefits of VEGF-induced myocardial angiogenesis", <i>Nature Medicine</i> , 1995, pp. 1085-1089, Vol. 1, No. 10.	
	24	TAKESHITA et al., "A single intraarterial bolus of vascular endothelial growth factor augments revascularization in a rabbit ischemic hind limb model", <i>J. Clin. Invest.</i> , 1994, pp. 662-670, Vol. 93.	
	25	HENDEL et al., "Effect of intracoronary recombinant human vascular endothelial growth factor on myocardial perfusion", <i>Circulation</i> , 2000, pp. 118-121, Vol. 101, No. 2.	
	26	SCHWARTZ et al., "Evaluation of the effects of intramyocardial injection of DNA expressing vascular endothelial growth factor (VEGF) in a myocardial infarction mdoel in the rat - angiogenesis and angioma formation", <i>J. Amer. College of Cardiology</i> , 2000, pp. 1323-1330, Vol. 35, No. 5.	
EXAMINER		DATE CONSIDERED	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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SHEET 3 of 3

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First Named Inventor	Ji-In Kim Almstead
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	27	SHWEIKI et al., "Vascular endothelial growth factor induced by hypoxia may mediate hypoxia-initiated angiogenesis", Letters to Nature, 1992, pp. 843-845, Vol. 359.	
	28	LEVY et al., "Transcriptional regulation of the rat vascular endothelial growth factor gene by hypoxia", Drug Disc. Today, 1995, pp. 13333-13340, Vol. 270, No. 22.	
	29	IKEDA et al., "Hypoxia-induced transcriptional activation and increased mRNA stability of vascular endothelial growth factor in C6 glioma cells", J. Biol. Chem., 1995, pp. 19761-19766, Vol. 270, No. 34.	
	30	LEVY et al., "Post-transcriptional regulation of vascular endothelial growth factor by hypoxia", Drug Disc Today, 1996, pp. 2746-2753, Vol. 271, No. 5.	
	31	AGANI et al., "Mersalyl is a novel inducer of vascular endothelial growth factor gene expression and hypoxia-inducible factor 1 activity", Mol. Pharmacol., 1998, pp. 749-754, Vol. 54.	
	32	BROGI et al., "Indirect angiogenic cytokines upregulate VEGF and bFGF gene expression in vascular smooth muscle cells, whereas hypoxia upregulates VEGF expression only", Circulation, 1994, pp. 649-652, Vol. 90.	
	33	VAN BELLE et al., "Potentiated angiogenic effect of scatter factor/hepatocyte growth factor via induction of vascular endothelial growth factor", Circulation, 1998, pp. 381-390, Vol. 97, No. 4.	
	34	SEMENZA, "Regulation of erythropoietin production", Hematol. Oncol. Clin. N. Amer., 1994, pp. 863-885, Vol. 8, No. 5.	
	35	SEMENZA et al., "Transcriptional regulation of genes encoding glycolytic enzymes by hypoxia-inducible factor 1", J. Biol. Chem., 1994, pp. 23757-23763, Vol. 269, No. 38.	
	36	KRANZ, "Blood", J. of Amer. Society of Hematology, 1991, pp. 419-434, Vol. 77, No. 3.	
	37	QUROSHI et al., "Mimicry of erythropoietin by a nonpeptide molecule", PNAS, 1999, pp. 12156-12161, Vol. 96, No. 21.	

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